



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/597,718

09/14/2006

Hee Kyung Park

117-06

5322

23713

7590

06/22/2010

GREENLEE WINNER AND SULLIVAN P C

4875 PEARL EAST CIRCLE

SUITE 200

BOULDER, CO 80301

EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,718	Applicant(s) PARK ET AL.	
	Examiner Ethan Whisenant	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 12-14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 6-10, 12-14 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

NON-FINAL ACTION

1. The applicant's response (filed 18 MAY 2010) has been entered. Following the entry of the claim amendment(s), **Claim(s) 6-10, 12-14 and 17-22** is/are pending. **The Finality of the previous Office action is withdrawn in order to make a new grounds of rejection.**

35 USC § 112- 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

3. **Claim(s) 6-10, 12-14 and 17-22** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the metes and bounds are not clearly recited and therefore it is unclear what is intended. Does this method require that each of the QC probe and the QC probe which acts as a target probe comprise a fluorescent material having a different excitation/emission wavelength from a fluorescent material for the target probe? This claim could be interpreted as if the QC probe which acts as a target probe need not be labeled. Stated another way, the claim could be interpreted as if only the QC probe and the target probe need be labeled. Note that the last phrase of Claim 6 only requires that the QC probe have the same base sequence as that of the target probe and that the QC probe and the target probe be labelled with fluorescent material having a different excitation/emission wavelength from each other. Nothing is

Art Unit: 1634

said about the the QC probe which acts as a target probe. For at least the reasons recited, the language used is confusing and therefore indefinite. Is not a QC probe which acts as a target probe simply a target probe? Please clarify.

Claim 9 is confusing and thererfor indefinite for the same reason(s) recited against Claim 6 above..

35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1634

35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

5. **Claim(s) 9-10 and 20-22** is/are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. [US 7,053,180 (2006)].

Claim 9 is drawn to a microarray having immobilized thereon a spacer base and a quality control probe (QC probe) and a target probe or a QC probe which acts as a target probe. The QC probe and the target probe must have the same base sequence as that of the target probe but must be labelled with fluorescent material having a different excitation/emission wavelength from that of the target probe. One possible interpretation of Claim 9 is as follows: "A microarray having immobilized

Art Unit: 1634

thereon a spacer base and first and second oligonucleotide probes which probes are identical in sequence and which are labeled with first and second fluorophores wherein said first and second fluorophores have different excitation/emission wavelengths". Note both of the interpretations set forth above are made in light of the ambiguity of Claim 9 as outlined above in the 112, 2nd paragraph rejection.

Johnson et al. teach an array comprising all of the structural limitations set forth in Claim 9, see especially Column 21, beginning at about line 39 to at least line 53. Here Johnson et al; describe an microarray which at the end of the hybridization step comprises all of the structural limitations recited in Claim 9. Without defining in the claim what is meant by "oligonucleotide" and/or "probe" the examiner has given these terms their broadest reasonable meaning. It was well known and routine in the art to define an oligonucleotides and/or probes as either a single stranded molecule of two or more nucleotides or a double stranded molecule of two or more nucleotides.. On the array of Johnson et al. at the end of the hybridization step, the oligonucleotides are double stranded and differentially labeled. At a given spot of the microarrays of Johnson et al, at the end of the hybridization step approximately half of the the immobilized probes will be hybridized to Cy3 label nucleic acids while the other half will be hybridized to Cy5 label nucleic acids which as described by Johnson et al.results in a distinct combined fluorescence. Johnson et al. do not teach inspecting the quality of a microarray as applicant teaches, however, it is asserted that that limitation is directed to an intended use and thus fails to futher limit the claimed microarray. Likewise the limitation in Claim 9 which reads " wherein the QC probe or the QC probe which acts target probe comprise an oligonucleotide labelled at one or more positions with a fluorescent material having a different excitation/emission wavelength from a fluorescent material labelled in the target material" is an intended use limitation and does not further limit the compsition claimed. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA

Art Unit: 1634

1963). As regards the limitation "a spacer base" it is asserted that either the 5' most or the 3' most base which ever is used by Johnson et al. to attach their probes to the solid support used, meets this limitation. Furthermore, the use of spacers (i.e. linkers) to attach probes to solid surfaces or labels to probes was well known in the art at the time of the invention (Official Notice), See for example Saiki et al. (1989) who teach a long tail of T nucleotides (i.e. 400 bp or more) used to attach their probes to the solid supports used..

Claim 10 is drawn to an embodiment of the the microarray of Claim 9 wherein the QC probe and the target probe are simultaneously immobilized on one spot.

For at least the reasons recited above against Claim 9 this limitation is considered inherent to Johnson et al.

Claim 20 is drawn to an embodiment of the the microarray of Claim 9 said fluorescent material is positioned at a 3'-end, a 5'end or at an internal position of the QC probe.

For at least the reasons recited above against Claim 9 this limitation is considered inherent to Johnson et al. as the probe oligonucleotides are labeled at some position. Furthermore, it was routine to label oligonucleotides at their termini (i.e. at a 3' end and/or at a 5'end).

Claim 21 is drawn to an embodiment of the the microarray of Claim 9 wherein a spacer is further included between the probe sequence and the fluorescent material.

Johnson et al. do not explicitly teach a using a spacer between the probe sequence and the fluorescent material, however, as argued above spacers (e.g. linkers) were well known in the art at the time of the invention as was their use to facilitate the attachment of label moieties to oligonucleotides, see for example, ¶[0081] of Lokhov et al. [US 2003/0235822] Therefore, absent an unexpected result it would have been

Art Unit: 1634

prima facie obvious to one of ordinary skill in the art at the time of the invention to modify the method/array of Johnson et al. wherein the fluorescent materials are attached to the oligonucleotides via a spacer.. Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

Claim 22 is drawn to an embodiment of the the microarray of Claim 9 wherein the fluorescent material is at least one material selected from a defined group which includes Cyanine 3 and Cyanine 5.

Johnson et al. teach these limitations, see Column 21.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

6. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1634

CONCLUSION

7. Claim(s) 6-10, 12-14 and 17-22 is/are rejected and/or objected to for the reason(s) set forth above.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30 am -5:30 pm EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634